IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Attorney Docket No. C1190/20009)

First Named Inventor: Laurent Di Constanzo	)	Confirmation No. 7903
Serial No.: 09/914,544	)	Before the Examiner: Oh, Simon J.
Filed: March 19th, 2002	)	
For: Orally Dispersable Tablet with Low Friability and Method for Preparing Same	)	Art Unit: 1618

DECLARATION UNDER RULE 132

To Honorable Commissioner of Patents and Trademarks
Washington, D.C.

Sir :

I, Edouard Gendrot, of 24 rue de Dreux, 28500, GARNAY, FRANCE do solemnly declare :

THAT I have been working with ETHYPHARM S.A. since May 5th, 1990 and that I now hold the position of Production Manager;

THAT, I am a named inventor on the present patent application n° 09/914,544, and that I am fully familiar therewith ;

THAT, I have read and understood the Office Action of April 12, 2007 in connection with the present patent application ;

THAT, I have read and understood Hunter *et al.* (US 6,391,337), Schmitz *et al.* (US 6,079,968) and Valentine (US 4,684,534) ;

THAT, the experiments described in the attached test report were carried out under my supervision;

THAT, the directly compressible tablets were prepared using coated paracetamol as the active ingredient, direct compressed mannitol and crystalline powder mannitol as the soluble agent, crospovidone as the disintegrating agent, a sweetener, a flavour, and magnesium stearate as the lubricating agent;

THAT, the tablets of Hunter *et al.* are coated and thus not susceptible to friability when removed from the blisters in which they are packed, in contrast to the directly compressible tablets of the present patent application;

THAT, tablets of the present patent application were prepared by applying the lubricating agent (i.e. magnesium stearate) on the external surface of the punches;

THAT, due to the application of the lubricating agent on the surface of the tablet, the friability of the tablets of the present patent application is less than 1%;

THAT, the disintegration time of the tablets of the present patent application is not negatively affected by the application of the lubricating agent on the external surface of the tablets, on the contrary the

disintegration time is in fact increased by such an application;

I, the undersigned, declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and, further, that these statements were made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001, of Title 18, of the United States Code, and that such wilful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date:

Edouard Gendrot

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Attorney Docket No. C1190/20009)

First Named Inventor: Laurent Di Constanzo	)	Confirmation No. 7903
Serial No.: 09/914,544	)	Before the Examiner: Oh, Simon J.
Filed: March 19th, 2002	)	
For: Orally Dispersable Tablet with Low Friability and Method for Preparing Same	)	Art Unit: 1618

TEST REPORT

Tablets were prepared according to the following formula:

Coated Paracetamol	548,70 mg
Direct compression mannitol	514,80 mg
Crystalline powder mannitol	171,50 mg
Crospovidone	120,00 mg
Aspartame	40,00 mg
Banana flavouring	5,00 mg
Magnesium stearate	0,90 mg

Tablets were prepared as follows:

The coating was prepared according to Example 1 of European Patent EP1156786. In particular, microcrystals of paracetamol were fed into a fluid-bed plant and a dispersion of Eudragit E 100, Eudragit NE 30 D and colloidal silica in ethanol was sprayed onto the microcrystals to obtain microcrystals coated with 10% of polymer with the following formula:

Coated Paracetamol	500,00 mg
Eudragit NE 30 D (dry)	12,10 mg
Eudragit E 100	24,30 mg
Colloidal silica1	2,30 mg

Two series of tablets were prepared:

- Tablets C1 were prepared by introducing 1% by weight with respect to the weight of the tablet of magnesium stearate with the other excipients before compression.

- Tablets C2 were prepared by applying 0,07% by weight with respect to the weight of the tablet of magnesium stearate on the external surface of the punches.

Tablets C1 and C2 were prepared on a FETTE P2100 rotary compressing machine equipped with 29 polo punches of 17 mm in diameter.

The results are presented in the following table:

	Tablet C1	**Tablet C2**
Compression Force	17-22 kN/punch	11 kN/punch
Hardness	30 N	65 N
Disintegration time	35 sec.	18 sec.
Friability	1,3%	0.3%

The disintegration time corresponds to the time that separates, on the one hand, the moment at which the tablet is placed in the mouth in contact with the saliva and, on the other hand, the moment of the swallowing resulting from the tablet's disintegration on contact with the saliva.

The friability was measured according to the procedure described in the French Pharmacopea (X^e ed., "V.5.1-friability des comprimés", January 1993 with the help of a blade apparatus.

Respectfully submitted